

Regulation (EC) No 1924/2006 – nutrition and health claims on foods

- Update on Article 13(1) list of health claims



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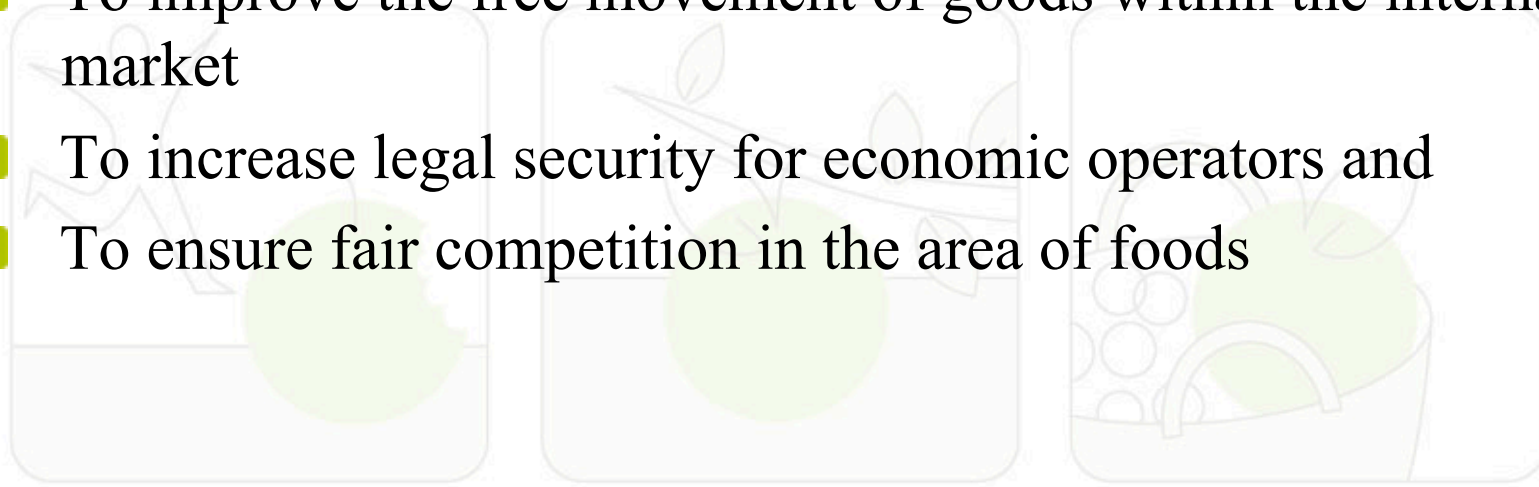
Adoption

- Commission proposal adopted in July 2003
- Adoption of Regulation 1924/2006 in second reading 20 December 2006
- Entered into force 19 January 2007
- Applicable from 1 July 2007
- Amendments adopted by co-decision
 - Comitology alignment
 - Transition period for children claims



Objectives of the Regulation

- To achieve a high level of consumer protection
- To improve the free movement of goods within the internal market
- To increase legal security for economic operators and
- To ensure fair competition in the area of foods





Health claims *shall*:

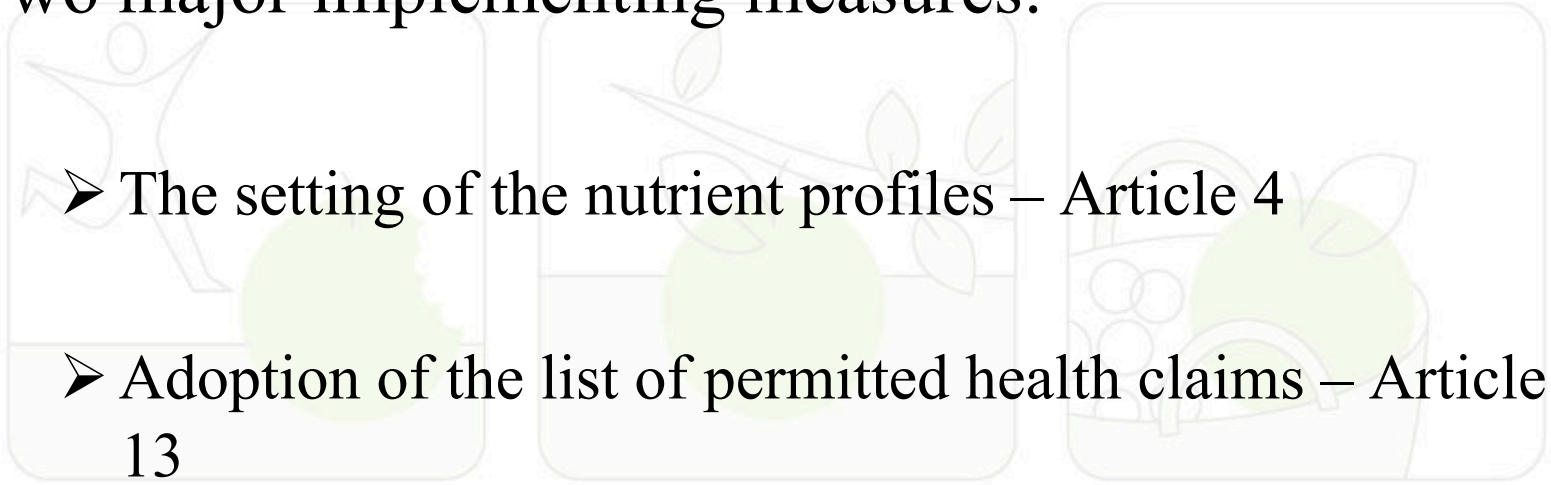
“be based on and substantiated by generally accepted scientific evidence”

Health claims *shall not*:

- “be false, ambiguous or misleading”
- “give rise to doubt about the safety and/or the nutritional adequacy of other foods”
- “encourage or condone excess consumption of a food”
- “state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general”
- “exploit fear in the consumer”

- Understandable for the average consumer

Two major implementing measures:

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- The setting of the nutrient profiles – Article 4
 - Adoption of the list of permitted health claims – Article 13



Authorisation procedures

Different types of claims => Different procedures for authorisation

“Function” claims:

- Article 13 procedure (compilation of Community list of permitted health claims)
- Additions: *“new developed scientific evidence and/or based on proprietary data”*

Reduction of disease risk claims and claims referring to children’s development and health:

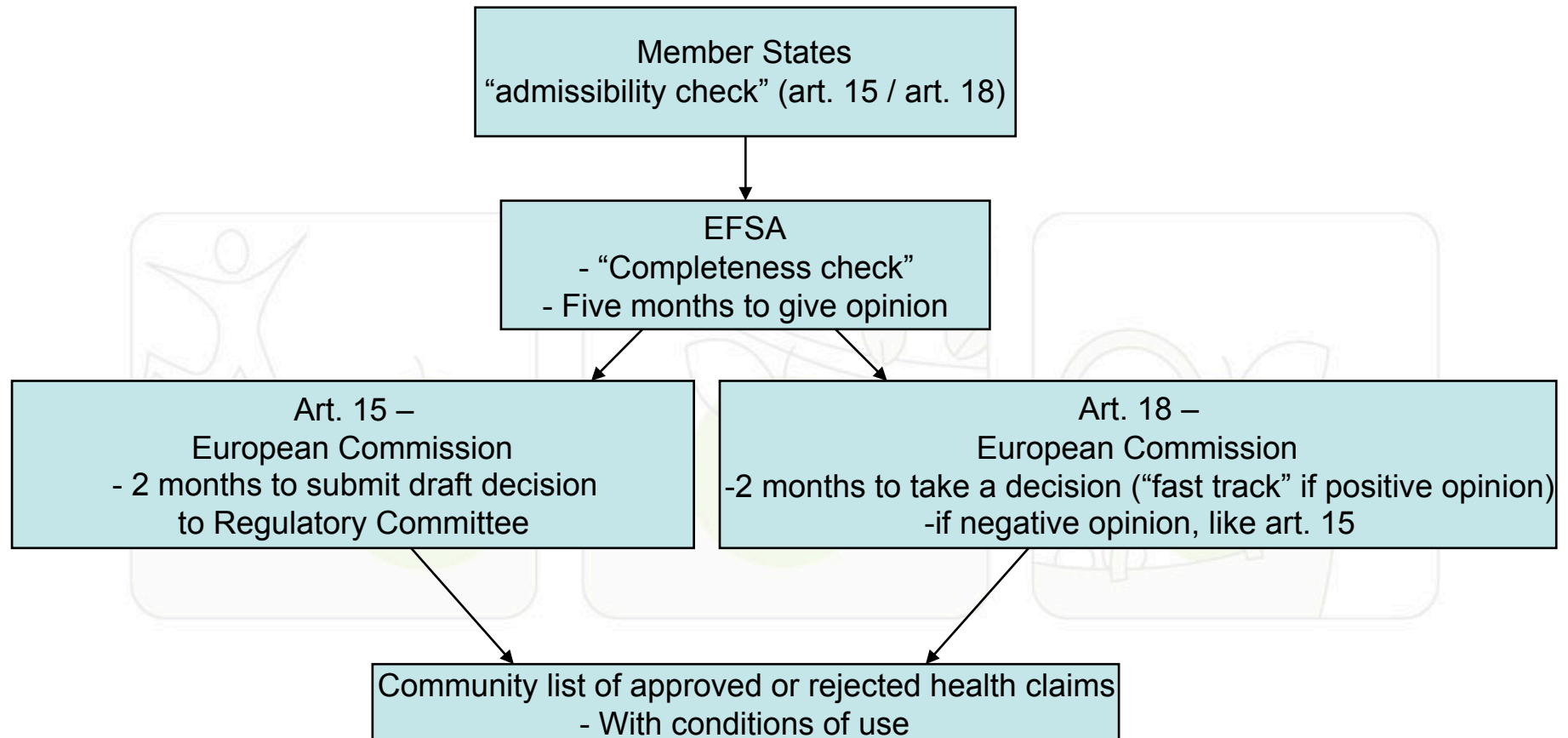
- individual authorisation procedure

Nutrition claims:

- no authorisation procedure



Procedures for authorisation





Steps for the Community list

- Member States submitted national lists – 31 January 2008
- National responsibility, but efforts to coordinate to ensure coherence
- Member States and stakeholders consulted in June/July 2008 (DG SANCO Advisory Group consulted 8 July 2008)
- Consolidated list submitted to EFSA 31 July 2008 together with ToR
- Revised consolidated list submitted to EFSA Nov + Dec 2008
- Clarification process in 2009 – 2145 health claims sent back to the MS and now returned to EFSA (more than 600 without any clarification)
- List to be adopted by Regulatory Committee – 31 January 2010



Member States lists

31 January 2008 a total of;

- 44000 health claims...
- Many, many more examples of wordings...

...were submitted by the Member States

- The consolidated list with 4185* health claims (main entries) was forwarded to EFSA in 3 batches (July, Nov and Dec 2008)
- On-going effects to finalise the consolidated list: Addendum, removing non eligible claims (e.g. product specific claims)

*4185 minus the withdrawn claims



Overall question to EFSA cf. Art 13(3):

- Is the beneficial effect of the food on the function substantiated by *generally accepted scientific evidence* by taking into account the *totality* of the available scientific data, and by *weighing* the evidence?
- Does the wording reflect the scientific evidence?



State of play...

- EFSA published opinions in series – first 1st of October 2009
- Commission will propose to the Member States a process facilitating a progressive adoption of the Community list of permitted health claims.
- Health claims not backed by science will progressively be included into a Community Register with the list of health claims that cannot be used on the market – 6 months transition period.



First series of EFSA opinions (1st Oct, 2009)

- More than 500 claims evaluations adopted for over 200 foods/constituents (published 1 October, 2009)
- For the health claims for which EFSA clearly concluded that there is scientific evidence we will proceed to consider them for the list of authorised claims.
- For the health claims for which EFSA clearly concluded that there is no scientific evidence we will proceed to consider them for the list of rejected claims.
- For the health claims for which the EFSA conclusions for different reasons are not clearly pointing in either of the two directions we are reflecting on the appropriate ways forward.



Art 13(5) / 14 authorizations

EFSA has received app. 280 applications

- 213 children's claims
- 47 risk reduction claims
- 21 newly developed science/proprietary data

- Commission has received 73 EFSA opinions
- Applicant/public has opportunity to provide comments to the Commission
- Commission asks EFSA to provide input on comments of scientific nature

Until now the Standing Committee (SCFCAH) voted in favour of draft Commission Regulations that:

■ Permit:

- 4 claims referring to reduction of a disease risk factor (Art. 14(1)(a))

- 6 claims referring to children's development and health (Art. 14(1)(b))

■ Reject:

- 6 claims under Art. 14 (1)(a)
- 28 claims under Art. 14 (1)(b)

■ Reject:

- 10 claims under Art. 13(5)

⇒ 10 permitted and 44 rejected claims (register on website)

⇒ 18 applications under consideration – including DHA, ALA claims and an Art 13(5) application positively assessed by EFSA

Issues emerged/debated

- wording of the claims - fixed or flexible?
A certain flexibility provided for in the recitals
- claims about reduction of a risk factor of a disease not reduction of a disease
- Claims relating to nutrient/substance, food or category of foods versus branded product
- EFSA assessment unduly severe
- Sterol/stanol effect on cholesterol reduction – matrix, magnitude and duration

Other issues in the claims area:

- Member States admissibility Guidance
- Guidance on the correct use of authorised claims
- Proprietary data – exclusive right of use
- Revision of the annex – Favourable vote in the SCOFCAH
1st October 2009:
 - Source of omega-3 fatty acids
 - High in omega-3 fatty acids
 - High in monounsaturated fat
 - High in polyunsaturated fat
 - High in unsaturated fat- further discussions on other claims...
- Nutrient profiles...

Thank you for your attention!

